



Dkt. 0028/71160/JPW/BJA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Veneta Hanson and Harry Spiera  
Serial No.: 10/676,691  
Filed : September 30, 2003  
For : DIAGNOSTIC TEST FOR NEUROPSYCHIATRIC SYSTEMIC  
LUPUS ERYTHEMATOSUS

1185 Avenue of the Americas  
New York, New York 10036  
March 4, 2005

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Arlington, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. § 1.56, applicants direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (Exhibit A) and attached hereto as Exhibits 1-13:

- 1) Bresnihan, B. et al., (1979), An Antineuronal Antibody Cross-Reacting with Erythrocytes and Lymphocytes in systemic Lupus Erythematosus, *Arthritis and Rheumatism*, 22(4):313-320; (Exhibit 1)
- 2) Burton, R. et al., (1971), Immunological Disorders of the Nervous System, *Res. Publ. Assoc. Res. Nerv. Ment. Dis.*, 49:197-214; (Exhibit 2)
- 3) Denburg, J. et al., (1983), The Pathogenesis of Neuropsychiatric Lupus, *Can. Med. Assoc. J.*, 128:257-260;

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(Exhibit 3)

- 4) Gitlits, V. et al., (1997), Autoantibodies to Evolutionarily Conserved Epitopes of Enolase in a Patient with Discoid Lupus Erythematosus, *Immunology*, 92:362-368; (Exhibit 4)
- 5) Gitlits, V. et al., (2001), Disease Association, Origin, and Clinical Relevance of Autoantibodies to the Glycolytic Enzyme Enolase, *J. Inv. Med.*, 49(2):138-145; (Exhibit 5)
- 6) Hanson, V. et al., (1992), Systemic Lupus Erythematosus Patients with Central Nervous System Involvement Show Autoantibodies to a 50-kD Neuronal Membrane Protein, *J. Exp. Med.*, 176:565-573; (Exhibit 6)
- 7) Johnson, R. et al., (1968), The Neurological Manifestations of Systemic Lupus Erythematosus, *Medicine*, 47(4):337-369; (Exhibit 7)
- 8) Krüger, K. (1984), Lupus Erythematosus Und Zentralnervensystem; (Exhibit 8)
- 9) López-Méndez, A. et al., (1986), Neurological Involvement in Systemic Lupus Erythematosus, Immunological and Clinical Aspects, *Bol. Asoc. Med. P. Rico*, 78(3):99-103; (Exhibit 9)
- 10) Pratesi, F. et al., (2000), Autoantibodies Specific for  $\alpha$ -Enolase in Systemic Autoimmune Disorders, *J. Rheum.*, 27:109-115; (Exhibit 10)

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Page 3

- 11) Quismorio, F. et al., (1972), Antibodies Reactive with Neurons in SLE Patients with Neuropsychiatric Manifestations, *Int. Arch. Allergy*, 43:740-748; (Exhibit 11)
- 12) Schott, K. et al., (1998), Antibrain Antibodies in Mental Disorder: No evidence for Antibodies Against Synaptic Membranes, *J. Neural. Transm.*, 517-524; (Exhibit 12) and
- 13) Wilson, H. (1979), Association of IgG Anti-Brain Antibodies with Central Nervous System Dysfunction in Systemic Lupus Erythematosus, *Arthritis and Rheumatism*, 22(5):458-462. (Exhibit 13)

Applicants note that Exhibit 8 is published in German. In accordance with 37 C.F.R. §1.98(a)(3)(i), a concise explanation of the relevance of the content of the information of the reference is attached hereto as Exhibit B.

This Information Disclosure Statement is being submitted under 37 C.F.R. §1.97(b).

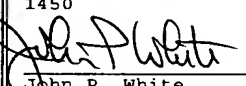
Applicants request that the Examiner review the publications and make them of record in the subject application.

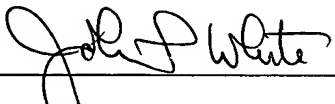
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

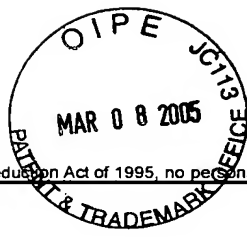
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No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
	3/4/05
John P. White Reg. No. 28,678	Date

  
John P. White  
Registration No. 28,678  
Attorney for Applicants  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
(212) 278-0400



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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

### Complete if Known

Application Number	10/676,691
Filing Date	September 30, 2003
First Named Inventor	Veneta Hanson
Art Unit	
Examiner Name	
Attorney Docket Number	0028/71160/JPW/BJA

Sheet 1 of 2

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1	Bresnihan, B. et al., (1979), An Antineuronal Antibody Cross-Reacting with Erythrocytes and Lymphocytes in systemic Lupus Erythematosus, Arthritis and Rheumatism, 22(4):313-	
	2	Burton, R. et al., (1971), Immunological Disorders of the Nervous System, Res. Publ. Assoc. Res. Nerv. Ment. Dis., 49:197-214;	
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	6	Hanson, V. et al., (1992), Systemic Lupus Erythematosus Patients with Central Nervous System Involvement Show Autoantibodies to a 50-kD Neuronal Membrane Protein, J. Exp. M	
	7	Johnson, R. et al., (1968), The Neurological Manifestations of Systemic Lupus Erythematosus, Medicine, 47(4):337-369;	
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	10	Pratesi, F. et al., (2000), Autoantibodies Specific for •-Enolase in Systemic Autoimmune Disorders, J. Rheum., 27:109-115;	

Examiner Signature		Date Considered	
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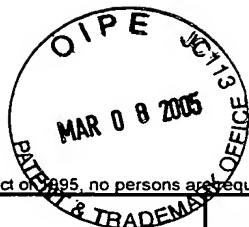
\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Applicants: Veneta Hanson et al.  
U.S. Serial No.: 10/676,691  
Filed: September 30, 2003  
Exhibit A



PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
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	11	Quismorio, F. et al., (1972), Antibodies Reactive with Neurons in SLE Patients with Neuropsychiatric Manifestations, Int. Arch. Allergy, 43:740-748;	
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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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While autoantibodies to neuronal structures are not exclusive to SLE, these observations closely suggest that, in addition to vascular alterations, the pathogenesis of neuropsychiatric SLE syndrome is based on autoimmune mechanisms leading to functional and/or structural alteration of the neuronal cells or their membrane components. In the following fig. 1 an attempt is made to present a pathophysiological model of cerebral lupus. At this time it is not evident whether beyond the above, the mediator substances released during the immune reactions have an additional pathogenic significance.